

State Board of Health

12 VAC 5-408

**Rules and Regulations for Certification of Quality Assurance
for Managed Care Health Insurance Plan Licensees**



Center for Quality Health Care Services and Consumer Protection
Virginia Department of Health
3600 West Broad Street, Suite 216
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Center for Quality Health Care Services and Consumer Protection

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PART I.
Definitions and General Information.

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12 VAC 5-408-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Adverse decision" means a utilization review determination by the utilization review entity that a health service rendered or proposed to be rendered was not or is not medically necessary, when such determination may result in noncoverage of the health service or health services. When the policy, contract, plan, certificate, or evidence of coverage includes coverage for prescription

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drugs and the health service rendered or proposed to be rendered is a prescription for the alleviation of cancer pain, any adverse decision shall be made within 24 hours of the request for coverage.

"Appeal" means a formal request by a covered person or a provider on behalf of a covered person for reconsideration of a decision, such as a final adverse decision, a benefit payment, a denial of coverage, or a reimbursement for service.

"Basic health care services" means those health care services, as applicable to the type of managed care health insurance plan, described in § 38.2-5800 of the Code of Virginia which are required to be provided, arranged, paid for, or reimbursed by the managed care health insurance plan licensee for its covered persons.

"Board" means the Board of Health.

"Bureau of Insurance" means the State Corporation Commission acting pursuant to Title 38.2 of the Code of Virginia.

"Center" means the Center for Quality Health Care Services and Consumer Protection of the Virginia Department of Health.

"Certificate" means a certificate of quality assurance.

"Complaint" means a written communication from a covered person primarily expressing a grievance. A complaint may pertain to the availability, delivery, or quality of health care services including claims payments, the handling or reimbursement for such services, or any other matter pertaining to the covered person's contractual relationship with the MCHIP.

"Covered person" means an individual residing in the Commonwealth, whether a subscriber, policyholder, enrollee, or member, of a managed care health insurance plan (MCHIP), who is entitled to health services or benefits provided, arranged for, paid for, or reimbursed pursuant to an MCHIP.

"Delegated service entity" means the entity with which an MCHIP licensee contracts to provide one or more of the services listed in 12 VAC 5-408-320 A for one or more of its MCHIPs, pursuant to and in accordance with the provisions of Part VI (12 VAC 5-408-320 et seq.) of this chapter, inclusive.

"Department" means the Virginia Department of Health.

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"Emergency services" means those health care services that are rendered by affiliated or nonaffiliated providers after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected to result in (i) serious jeopardy to the mental or physical health of the individual, (ii) danger of serious impairment of the individual's bodily functions, (iii) serious dysfunction of any of the individual's bodily organs, or (iv) in the case of a pregnant woman, serious jeopardy to the health of the fetus. Emergency services provided within an MCHIP's service area shall include covered health services from nonaffiliated providers only when delay in receiving care from a provider affiliated with the MCHIP could reasonably be expected to cause the covered person's condition to worsen if left unattended.

"Evidence of coverage" means any certificate, individual or group agreement or contract, or identification card or related document issued in conjunction with the certificate, agreement or contract, issued to a covered person setting out the coverage and other rights to which a covered person is entitled.

"Final adverse decision" means a utilization review determination made by a physician advisor or peer of the treating health care provider in a reconsideration of an adverse decision, and upon which a provider or patient may base an appeal.

"Health care data reporting system" means the state contracted integrated system for the collection and analysis of data used by consumers, employers, providers, and purchasers of health care to continuously assess and improve the quality of health care in the Commonwealth.

"Managed care health insurance plan" or "MCHIP" means an arrangement for the delivery of health care in which a health carrier, as defined in § 38.2-5800 of the Code of Virginia, undertakes to provide, arrange for, pay for, or reimburse any of the costs of health care services for a covered person on a prepaid or insured basis which (i) contains one or more incentive arrangements, including any credentialing requirements intended to influence the cost or level of health care services between the health carrier and one or more providers with respect to the delivery of health care services and (ii) requires or creates benefit payment differential incentives for covered persons to use providers that are directly or indirectly managed, owned, under contract with or employed by the health carrier. Any health maintenance organization as defined in § 38.2-4300 of the Code of Virginia or health carrier that offers preferred provider contracts or policies as defined in § 38.2-3407 of the Code of Virginia or preferred provider subscription contracts as defined in § 38.2-4209 of the Code of Virginia shall be deemed to be offering one or more managed care health insurance plans. For the purposes of this definition, the prohibition of balance billing by a provider shall not be deemed a benefit payment differential incentive for covered persons to use providers who are directly or indirectly managed, owned, under contract with or employed by the health carrier. A single managed care health insurance plan may encompass multiple products and multiple types of benefit payment differentials; however, a

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single managed care health insurance plan shall encompass only one provider network or set of provider networks.

"Managed care health insurance plan licensee" or "MCHIP licensee" means a health carrier subject to licensure by the Bureau of Insurance and to quality assurance certification by the department under Title 38.2 of the Code of Virginia who is responsible for a managed care health insurance plan in accordance with Chapter 58 (§ 38.2-5800 et seq.) of Title 38.2 of the Code of Virginia.

"Material" means that which has an effective influence or bearing on, or is pertinent to, the issue in question.

"Medical necessity" or "medically necessary" means appropriate and necessary health care services which are rendered for any condition which, according to generally accepted principles of good medical practice, requires the diagnosis or direct care and treatment of an illness, injury, or pregnancy-related condition, and are not provided only as a convenience.

"Nationally recognized accrediting body" means an organization that sets national standards specifically governing healthcare quality assurance processes, utilization review, provider credentialing, as well as other areas covered by this chapter and provides accreditation to managed care health insurance plans pursuant to national standards. The following entities shall be considered nationally recognized accrediting bodies:

1. The American Accreditation HealthCare Commission/URAC;
2. The National Committee for Quality Assurance (NCQA);
3. The Joint Commission on Accreditation of Healthcare Organizations, (JCAHO); and
4. Other nationally recognized accrediting bodies with national standards as described above that are accepted by the department.

"Person" means any individual, aggregate of individuals, association, business, company, corporation, joint-stock company, Lloyds type of organization, other organization, partnership, receiver, reciprocal or inter-insurance exchange, trustee or society.

"Plan of correction" means a an MCHIP'S written plan that outlines the action the MCHIP will take to address compliance issues identified during an administrative review or on-site examination conducted by the department.

"Preferred provider organization" or "PPO" means an arrangement in which a health carrier, as defined in § 38.2-5800 of the Code of Virginia, undertakes to provide, arrange for, pay for, or reimburse any of the costs of health care services, on an insured basis, which creates incentives, including financial incentives, for a covered person to use health care providers directly or

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indirectly managed, owned, under contract with, or employed by the health carrier, but shall not include a health maintenance organization as defined in § 38.2-4300 of the Code of Virginia.

"Quality assurance program" means the systems, standards and processes including, but not limited to, reasonable and adequate systems to assess, measure, and improve the health status of covered persons, necessary to obtain a certificate of quality assurance from the department in accordance with this chapter and in accordance with § 32.1-137.2 C of the Code of Virginia.

"Service area" means a geographic area as defined in § 38.2-5800 of the Code of Virginia.

"Timely" means the provision of services so as not to impair or jeopardize the integrity of the covered persons' diagnosis or outcomes of illness.

"Treating health care provider" means a licensed health care provider who renders or proposes to render health care services to a covered person.

"Utilization review" means a system for reviewing the necessity, appropriateness, and efficiency of hospital, medical or other health care services rendered or proposed to be rendered to a patient or group of patients for the purpose of determining whether such services should be covered or provided by an insurer, health services plan, managed care health insurance plan licensee, or other entity or person. For purposes of this chapter, "utilization review" shall include, but not be limited to, preadmission, concurrent and retrospective medical necessity determination, and review related to the appropriateness of the site at which services were or are to be delivered.

"Utilization review" shall not include (i) review of issues concerning insurance contract coverage or contractual restrictions on facilities to be used for the provision of services, (ii) any review of patient information by an employee of or consultant to any licensed hospital for patients of such hospital, or (iii) any determination by an insurer as to the reasonableness and necessity of services for the treatment and care of an injury suffered by an insured for which reimbursement is claimed under a contract of insurance covering any classes of insurance defined in §§ 38.2-117 through 38.2-119, 38.2-124 through 38.2-126, 38.2-130 through 38.2-132 and 38.2-134 of the Code of Virginia.

"Utilization review entity" means a person or entity performing utilization review.

"Utilization review plan" means a written procedure for performing a utilization review.

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12 VAC 5-408-20. Responsibility of the department.

A. The Code of Virginia allows the Board of Health to adopt regulations for the certification of quality assurance for managed care health insurance plans licensees. The Department of Health is charged with the responsibility for examining the quality of health care services provided by, arranged for, paid for, or reimbursed by managed care health insurance plan licensees according to regulations adopted by the board and any additional requirements that may be specified by the Code of Virginia. The Center for Quality Health Care Services and Consumer Protection acts as agent for the department for certifying managed care health insurance plans, which includes investigating complaints made against a MCHIP licensee.

B. In developing or revising these regulations, the department adheres to the requirements of the Administrative Process Act (§ 9-6.14:1 et seq. of the Code of Virginia) and the public participation process. The department solicits input from MCHIPs, associations of MCHIPs, providers, experts in related fields, advocacy organizations, consumers and the general public in the development or revision of this chapter through informal and formal comment periods and public hearings.

C. The department shall coordinate its activities with the Bureau of Insurance to ensure an appropriate level of regulatory oversight and to avoid undue duplication of effort or regulation.

12 VAC 5-408-30. Certificate of quality assurance.

A. A certificate for quality assurance shall be issued to managed care health insurance plan licensees. The commissioner shall issue or renew a certificate of quality assurance if the MCHIP licensee is in compliance with the applicable law and this chapter. On behalf of the commissioner, and under a written delegation of authority, the department shall examine the applicants and issue the certificates for quality assurance.

B. No certificate of quality assurance may be transferred or assigned without approval of the department.

C. Every certified MCHIP licensee shall file for its certificate of quality assurance with the department biennially, subject to payment of a fee and receipt of all material required by law and this chapter.

D. Upon request, the center will provide an application form for a certificate of quality assurance. The center shall consider the application complete when all the information

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requested and the application fee are submitted. If the center finds the application incomplete, the applicant will be notified in writing of receipt of the incomplete application.

E. The department shall send an application for renewal of a certificate to the licensee at least 90 days prior to the expiration date of the current certificate.

F. The department shall examine or review each applicant for an initial certificate of quality assurance and periodically for renewal thereof.

G. Upon receipt of a written request from the governing body of an MCHIP licensee, the commissioner, in her sole discretion, may consider a modification and issue a temporary or permanent variance in the application of one or more of these regulations provided patient safety, care, or the ability of an MCHIP licensee to provide, arrange for, or reimburse the cost of services will not be adversely affected. The written request shall identify the reason the MCHIP licensee cannot immediately comply with the specified regulation and how any proposed modification is equal to or will meet the intent of the regulation for which a variance is requested. Upon review of the request, the commissioner may grant a temporary variance for less than a full period of certification, or a permanent variance for a full period of certification, or deny the request. Any temporary or permanent variance granted by the commissioner shall be subject to review and renewal before a certificate renewal, extension or re-issuance is granted.

H. Upon the issuance or renewal of a certificate, the department, on behalf of the commissioner and under a written delegation of authority, shall provide a certificate of quality assurance to the MCHIP licensee and a copy to the Bureau of Insurance.

I. Upon determining to deny or refuse to renew a certificate, the department, on behalf of the commissioner and under a written delegation of authority, shall notify the applicant in writing stating the reasons for the denial of the certificate. A copy of the notification of denial shall be provided to the Bureau of Insurance.

J. Appeals from a notification of denial shall be brought by a certificate applicant pursuant to the process set forth in 12 VAC 5-408-140.

12 VAC 5-408-40. Fees.

A. The center shall collect a fee for each initial application and each renewal application. MCHIP licensees with multiple plans wishing to submit a separate application for each plan must include the appropriate fee for each application. Fees shall accompany the application and are not refundable.

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B. Fees shall be sufficient to cover reasonable costs for the administration of the quality assurance program.

C. Fees shall be based upon a percentage, not to exceed 1/10 of 1.0%, of the proportion of direct gross premium income on business done in this Commonwealth attributable to the operation of managed care health insurance plans in the preceding biennium not to exceed \$10,000 per plan submitted by the licensee for separate certification.

After July 2000, applicants proposing to offer MCHIP plans in the Commonwealth shall be assessed a flat fee of \$5,000 for the initial application for a certificate of quality assurance.

12 VAC 5-408-50. Compliance provisions appropriate for type of plan.

A. Managed care health insurance plan licensees that offer one or more PPO plans as defined in this chapter must require their PPO plans to only comply with the following sections:

1. Parts I (12 VAC 5-408-10 et seq.) and II (12 VAC 5-408-160 et seq.) of this chapter;
2. Part III (12 VAC 5-408-220 et seq.) of this chapter except for subdivision 1 of 12 VAC 5-408-220 and subdivisions 2 and 10 of 12 VAC 5-408-240;
3. 12 VAC 5-408-260 through 12 VAC 5-408-280 of this chapter except subsection E of 12 VAC 5-408-260, subsections D and E of 12 VAC 5-408-270 and subsection G of 12 VAC 5-408-280; and
4. Parts VI (12 VAC 5-408-320 et seq.) and VII (12 VAC 5-408-360 et seq.) of this chapter.

The MCHIP licensee may comply with 12 VAC 5-408-170, 12 VAC 5-408-200, as well as subdivisions A 2 through A 4 of this section, by demonstrating it operates a PPO plan in conformity with the standards of a nationally recognized accrediting body applicable to preferred provider organizations and acceptable to the department. While such demonstration shall be considered reasonable and adequate compliance for purposes of initial and renewal MCHIP certification, the department may employ a checklist to identify and determine compliance with specific statutory or regulatory requirements that are more stringent than the nationally recognized accrediting body standards.

B. Managed care health insurance plan licensees other than PPO plans, including health maintenance organizations, must comply with this entire chapter. The MCHIP licensee may comply with 12 VAC 5-408-170, 12 VAC 5-408-200, 12 VAC 5-408-210, as well as Parts III through VI (12 VAC 5-408-220 through 12 VAC 5-408-360) of this chapter by demonstrating that the MCHIP licensee operates in conformity with the standards of a nationally recognized

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accrediting body that are appropriate for the type of MCHIP corresponding to the licensee and acceptable to the department. Such demonstration shall be considered reasonable and adequate compliance for purposes of initial and renewal MCHIP certification. Nothing in the preceding sentences shall preclude the department from imposing further requirements if the regulatory requirements are more stringent than the nationally recognized accrediting body's standards

C. Accreditation by a nationally recognized accrediting body shall satisfy the department in demonstrating that the MCHIP licensee operates in conformity with the standards of a nationally recognized accrediting body as permitted under subsection A or B of this section, provided the MCHIP licensee follows the provisions of 12 VAC 5-408-100 to be eligible for exemption from examination. Otherwise, an MCHIP that is not accredited shall be subject to the triennial comprehensive onsite examination requirements of 12 VAC 5-408-90. Nothing in the preceding sentences shall preclude the department from imposing further requirements if the regulatory requirements are more stringent than the nationally recognized accrediting body's standards.

12 VAC 5-408-60. General examination process.

A. The commissioner shall cause MCHIP licensees to be examined or reviewed by the department according to Article 1.1 (§ 32.1-137.1 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia to:

1. Verify that an MCHIP qualifies for an initial or renewal certificate of quality assurance;
2. Investigate a complaint filed against an MCHIP licensee;
3. Determine compliance with this chapter and applicable law; and
4. Determine if the MCHIP licensee has successfully implemented corrective action following an examination, or as a result of disciplinary action or sanction.

B. Examinations may be conducted onsite at an MCHIP licensee's office and at the site of any delegated service provider. At its discretion, the department may choose to conduct an administrative review to evaluate the MCHIP for compliance with applicable law and this chapter. The MCHIP's examination may also include contractors with whom the licensee has agreements, contracts, or other arrangements to provide health care services for the MCHIP.

C. Any examiner authorized by the department shall, so far as necessary for the purposes of the examination or review, have access during regular business hours to the premises and to any books, records, files, or property of the licensee as far as they directly relate to this regulation and Articles 1.1 (§ 32.1-137.1 et seq.) and 1.2 (§ 32.1-137.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.

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All material copied, recorded, or received by the department from the MCHIP licensee shall be privileged and confidential and shall not be subject to subpoena.

D. The MCHIP licensee shall be responsible for ensuring that all examination materials are submitted to the department at the time specified for submission and that they are complete. Failure to submit all of the examination materials as required may delay processing or result in the denial of the issuance or renewal of the quality assurance certificate.

E. A summary report of an MCHIP licensee's examination shall become part of the department's public file on the MCHIP. A copy of the summary report shall be provided to the Bureau of Insurance.

F. The department shall consider an MCHIP licensee's initial examination for a certificate of quality assurance as an evaluation of the MCHIP's quality assurance program in order to determine if it has the structure, organization, and policies and procedures in place to provide and support quality improvement activities.

G. Information provided during any examination conducted regarding compliance with this chapter shall be accurate and truthful. The MCHIP licensee shall not provide the department with falsified information during any aspect of the examination process. The department shall construe any effort to provide falsified information as violation of the statute, and the MCHIP licensee shall be subject to disciplinary action. Falsification is defined for the purpose of this chapter as fabrication, in whole or in part, of any information provided by the MCHIP or the MCHIP licensee.

H. The refusal of any MCHIP licensee, by its officers, directors, employees or agents, to submit to examination or review or to comply with any reasonable written request of the examiners shall be grounds for suspension, revocation, denial, or nonrenewal of a certificate of quality assurance held by the licensee.

12 VAC 5-408-70. Administrative review.

A The initial examination shall be an administrative review of the application for certificate of quality assurance and supporting documentation that includes:

1. The items listed in subsections F, G, H, and I of 12 VAC 5-408-160, except that if the MCHIP is accredited by a nationally recognized accrediting body appropriate for the type of MCHIP and approved by the department, it shall not be required to include in its application the items listed in subdivisions F 5, G 2, G 3, G 7 and subsection I;

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2. A copy of the most recent accreditation report executive summary, as applicable issued to the MCHIP or to the MCHIP's licensee from a nationally recognized accrediting body that evaluates quality assurance programs, with the written corrective action response, if any;
3. For MCHIP licensees that have been cited by another state or the District of Columbia concerning their quality assurance program, a copy of the most recent report of an examination of the quality of health care provided by the MCHIP under similar laws and regulations of another state, with a copy of the written corrective action response, if any;
4. The most recent report of any examination of the quality assurance program provided by the MCHIP issued by a federal regulatory agency with similar laws and regulations. Submission of this report shall not be necessary if the MCHIP provides a copy of the report required by subdivision 2 of this subsection with the written corrective action plan, if any; and
5. The department may coordinate with the Bureau of Insurance to obtain information that may assist its review.

B. The administrative review examination shall be conducted within 45 business days of the receipt of all the documentation required by the department. The MCHIP licensee shall be notified in writing if additional information is needed to clarify the information submitted and the specific time period in which to submit the materials. Accreditation by a nationally recognized accrediting body appropriate to the type of MCHIP and acceptable to the department shall be sufficient to demonstrate compliance with state requirements pursuant to 12 VAC 5-408-50. Nothing in the preceding sentences shall preclude the department from imposing further requirements if the regulatory requirements are more stringent than the nationally recognized accrediting body's standards.

C. The MCHIP licensee shall be notified of the results of the administrative review examination within 60 business days from the receipt by the department of all of the required documents and related information.

The department, at its discretion, may extend, for up to an additional 30 days, the period of time within which to approve or disapprove the information submitted. Licensees shall be notified in writing of any such extension.

D. The department, at its discretion, may conduct an onsite examination of the MCHIP licensee's quality assurance program if, for example, during its conduct of the administrative review examination, the department determines that an onsite examination is warranted in order to determine the MCHIP licensee's compliance with applicable laws or this chapter.

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E. Licensees with MCHIPs that successfully complete the examination shall be issued a certificate of quality assurance. Licensees with MCHIPs that do not successfully complete the examination shall be denied a certificate of quality assurance. Licensees with more than one MCHIP requesting separate certificates for each MCHIP shall file a separate certificate of quality assurance application for any of their MCHIPs with an accompanying fee. Each of the licensee's MCHIPs that were filed with separate applications that successfully complete the examination shall be issued a certificate of quality assurance. Each of the licensee's MCHIPs that were filed with separate applications that do not successfully complete the examination shall be denied a certificate of quality assurance.

12 VAC 5-408-80. Renewal application.

A. Every MCHIP licensee shall request renewal of its certificate of quality assurance biennially with the department. The purpose of the renewal examination shall be to determine if the MCHIP has maintained compliance with applicable laws and regulations since the last certificate of quality assurance was issued or renewed, and whether the MCHIP is using its best efforts to meet its quality assurance goals as set forth in its quality assurance plan.

B. The renewal examination shall include an administrative review of the renewal application and supporting documentation that includes:

1. The items listed in subsections F, G, H, and I of 12 VAC 5-408-160, except that if the MCHIP is accredited by a nationally recognized accrediting body appropriate for the type of MCHIP and acceptable to the department, it shall not be required to include in its application the items listed in subdivisions F 5, G 2, G 3, G 7 and subsection I;

2. The annual complaint reports;

3. The MCHIP's formal written evaluations of its quality assurance program expectations for the time period since the MCHIP's last application for a certificate of quality assurance;

4. A copy of the most recent accreditation report executive summary, as applicable, issued to the MCHIP or to the licensee from a nationally recognized accrediting body that evaluates quality assurance programs if the report was issued after the issuance of the current certificate from the department, provided that resubmission of the most recent accreditation report previously submitted in the prior initial or renewal application shall not be required, unless there has been a completed accreditation survey since that time that has led to renewal, suspension, or denial of accreditation and the written corrective action plan in response to the report, if applicable, shall also be submitted;

5. For MCHIP licensees that have been cited by another state or the District of Columbia concerning the quality of health care provided or administered, a copy of the most recent report of an examination of the quality of health care of provided by the MCHIP under

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similar laws and regulations of another state or the District of Columbia, and a copy of the written corrective action response; and

6. A copy of the report of any examination of the MCHIP by a federal regulatory body with similar laws and regulations issued since the certificate of quality assurance was last issued or renewed, provided that submission of this report shall not be necessary if the MCHIP licensee submits a copy of the report required by subdivision 4 of this subsection.

C. In addition, the department shall consider the following in its renewal examination:

1. The report of any comprehensive onsite examination of the MCHIP or licensee if one was conducted during the renewal period; and

2. Any disciplinary actions or sanctions issued by the department pursuant to § 32.1-137.5 of the Code of Virginia or this chapter, or by the Bureau of Insurance in keeping with § 32.1-137.2 E of the Code of Virginia.

D. The department may consider a summary report of the analysis of any data required to be reported by state law or regulation to the Health Care Data Reporting System in its renewal examination.

12 VAC 5-408-90. Comprehensive onsite examination.

A. The comprehensive onsite examination represents a periodic quality assurance evaluation process designed to ensure that the MCHIP licensee has in place the appropriate systems and processes to meet the requirements set forth in this chapter.

B. A comprehensive onsite examination shall be conducted triennially except for MCHIPs that meet the criteria specified in 12 VAC 5-408-100 pertaining to nationally recognized accreditation.

C. The comprehensive onsite examination shall take place:

1. At a time established by the department with 90 days advance notification to the MCHIP licensee;

2. In conjunction with a Bureau of Insurance market conduct examination of the licensee; or

3. At the request of the MCHIP licensee in agreement with the department following the completion of an initial administrative review examination for certification in order to document any corrective action taken in response to the initial examination.

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At the department's discretion and in response to complaints against the MCHIP licensee or the MCHIP, the department may expand a complaint investigation to a comprehensive examination to determine compliance with the MCHIP laws and regulations if it appears that covered person's health and safety may be jeopardized.

D. The MCHIP licensee shall be notified in writing at least 60 90 days in advance of the comprehensive onsite examination and shall be provided with information regarding the parameters of the examination.

The final determination of when a comprehensive onsite examination shall be conducted rests with the department. However, the department will take into consideration mitigating circumstances presented by the MCHIP licensee.

E. The MCHIP licensee or the department may request a preexamination conference for the purpose of discussing preparations for the examination. The conference shall not be used for determining whether a plan needs to be examined or the frequency of an onsite comprehensive examination.

F. Prior to the comprehensive onsite examination, the MCHIP licensee shall make available to the department the results of a member satisfaction survey or other initiative conducted to obtain member input regarding the MCHIP licensee. If the MCHIP licensee did not conduct a member satisfaction survey or initiative, then the MCHIP licensee will publish public notice soliciting comments from the MCHIP's covered persons regarding satisfaction with the MCHIP.

G. The MCHIP shall be notified of the results of the comprehensive onsite examination within 60 business days of the final day of the examination. The department may choose to notify the MCHIP earlier than 60 days and require immediate corrective action or initiate administrative disciplinary hearings for findings of serious or substantial noncompliance with the law or the regulations that could jeopardize covered persons' health or safety.

H. Depending on the examination findings, the department shall:

1. Require a corrective action plan as specified in 12 VAC 5-408-110 with a time frame in which corrective action shall be completed and verified by the department;
2. Proceed with disciplinary action or sanctions as specified in 12 VAC 5-408-140; or
3. Notify the MCHIP licensee that it is fully and completely in compliance with all applicable regulations.

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I. If the MCHIP licensee applicant has achieved accreditation from a nationally recognized accreditation entity acceptable to the department, it will be exempt from the comprehensive on-site examination following receipt of all accreditation findings.

12 VAC 5-408-100. Examination by a nationally recognized accreditation organization.

A. The department shall accept the accreditation of a an MCHIP licensee or MCHIP by a nationally recognized accrediting body appropriate to the type of MCHIP and approved by the department in lieu of the triennial comprehensive onsite examination described in 12 VAC 5-408-90 under the following conditions:

1. Conditional or provisional accreditation may be considered acceptable for meeting the requirements of this chapter provided that a second examination by a nationally recognized accrediting body is scheduled and completed within 15 to 18 months of the date a decision for conditional or provisional accreditation is made by the accrediting body, and that the second examination leads to an accreditation status that is not conditional or provisional.

2. The MCHIP licensee shall release to the department a copy of a report or document from a nationally recognized accrediting body containing that body's final report, or evaluation of the MCHIP's compliance with accreditation standards. The department may, at its discretion and on a case-by-case basis, request from the licensee any and all reports, letters and memoranda issued by the nationally recognized accrediting body to the licensee regarding the licensee's accreditation application or its evaluation for accreditation. In the event a licensee is granted only conditional or provisional accreditation, any written materials generated by the licensee regarding corrective or remedial action to be taken for achieving compliance with the accreditation standards shall also be released to the department at the same time the nationally recognized accrediting body is notified. The MCHIP licensee shall forward copies of the executive summary of its accreditation report to the department within 10 days of receipt by the MCHIP licensee, unless otherwise directed by the department.

3. The MCHIP licensee notifies the department of the date of its accreditation examination.

The department reserves the right to conduct a comprehensive examination of an accredited MCHIP when it appears that the health and safety of the covered persons may be jeopardized.

B. Accreditation by a nationally recognized accrediting body will not be accepted in lieu of the comprehensive onsite examination unless the accreditation standards are appropriate for the type of plan seeking exemption from the department's comprehensive onsite examination.

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12 VAC 5-408-110. Corrective action procedures.

A. Within 30 business days of the conclusion of the examination, the department shall provide the MCHIP licensee with a written summary of violations of the regulations or laws and any factual findings used as a basis to determine that a violation has occurred.

B. The department shall require the MCHIP licensee to submit a written plan of correction specifying how each violation will be corrected along with the time frames for completion of each corrective action. A single plan of correction shall address all events associated with a given violation. The plan of correction, when required, shall be submitted by the MCHIP licensee within 20 business days of receipt of the notice of violation, or sooner, if the department determines that the violations jeopardize the safety of covered persons.

C. The plan of correction shall be approved when the MCHIP licensee demonstrates to the satisfaction of the department that compliance will be achieved. If the plan of correction is not approved, the department may request that an amended plan of correction be submitted within 10 business days, or sooner, if the department determines that the violations jeopardize the safety of covered persons.

D. The summary of violations and the plan of correction shall not be released as public information until the department has approved the plan of correction or, in the event no plan of correction is required, after 20 business days of receipt of the summary of violations by the MCHIP licensee, whichever is sooner.

E. Unless otherwise documented, the department will presume receipt of the summary of violations by the MCHIP licensee by the seventh business day when mailed return receipt requested.

F. Failure of the MCHIP licensee to successfully implement the written plan of correction within a specified time period may result in an administrative sanction.

12 VAC 5-408-120. Changes to geographic service areas.

A. No MCHIP shall operate in a manner that varies in a material manner with the geographic service area information submitted pursuant to this chapter. Any changes in such information which would result in operational changes that vary in a material manner with the information currently on file with the department shall be subject to the department's prior approval.

B. The request for a material change in a geographic service area shall include:

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1. A description of the current geographic service area including a map of the current service area, a list of current primary care and specialty physicians and other providers, and the number of covered persons by service area.

2. An explanation as to whether the MCHIP is requesting an expansion or a reduction in its service area.

3. Notification that the MCHIP licensee has inquired of the Bureau of Insurance as to whether or not the service area request constitutes a material change and the bureau's determination, if available.

4. If a service area expansion is proposed, then the following is required:

a. A description of the service area that includes a map of the geographic service area expansion, projections of new enrollment, a listing of new primary care and specialty providers and other providers and their locations, and physician capacity to accept the anticipated enrollment;

b. Information necessary to determine if the MCHIP licensee will be capable of conforming to the access, availability, and travel requirements of 12 VAC 5-408-260 and 12 VAC 5-408-270; and

c. The methodology used to determine that the current health care system in the proposed service area can support the expansion.

5. If a MCHIP is reducing or eliminating a service area, the following information is required:

a. A description of the service area being reduced or eliminated;

b. The reason for the reduction or elimination of the service area and the effective date on which health care services will no longer be available through the MCHIP; and

c. Any information required by the department to determine that MCHIP covered persons are ensured continuity of care during the transition.

C. If the department fails to act on a notice of material change within 30 days of receipt of filing all necessary information, the proposed changes shall be deemed approved. The department, at its discretion, may extend the period of time within which to approve or disapprove the proposed changes for up to an additional 30 days. Licensees shall be notified in writing of any such extensions.

12 VAC 5-408-130. Complaint system, complaint examination and investigation.

A. Each MCHIP licensee shall establish and maintain for each of its MCHIPs a complaint system approved by the department and the Bureau of Insurance to provide reasonable procedures for the resolution of complaints.

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B. The department, on behalf of the commissioner and in cooperation with the Bureau of Insurance, shall examine the complaint system for compliance of the system with applicable statutes and regulations and shall require corrections or modifications as necessary. The effectiveness of the complaint system in allowing covered persons, or their duly authorized representatives, to have issues regarding quality assurance appropriately resolved shall be assessed by the department.

C. The department has the responsibility to investigate complaints regarding quality of care violations filed by or on behalf of covered persons.

D. Every person from whom information is sought in an investigation of a complaint against an MCHIP licensee shall cooperate in producing, or allowing reasonable access during regular business hours to, the books, records, files, accounts, papers, documents, and any or all computer or other recordings of the licensee being examined or those of any person or delegated services entity delivering health care services under contract, affiliation, delegation or other arrangement. Information shall be limited to that which is relevant to the investigation in question.

E. Deficiencies found during a complaint investigation shall be corrected as required in 12 VAC 5-408-110.

F. When the investigation is complete, the MCHIP licensee and the complainant will be notified of the findings of the investigation.

12 VAC 5-408-140. Administrative sanctions.

A. Nothing in this part shall prohibit the department from exercising its responsibility and authority to enforce applicable law and this chapter including proceeding directly to imposition of administrative sanctions.

B. The department, in consultation with the Bureau of Insurance, may impose such administrative sanctions or take such actions as are appropriate for violation of any of the regulations or laws. Such sanctions include:

1. Imposing civil monetary penalties, which shall not exceed \$1,000 per incident of noncompliance, to a maximum of \$10,000 for a series of related incidents of noncompliance;
2. Placing a certificate holder on probation;
3. Temporarily suspending a certificate of quality assurance;
4. Temporarily restricting or prohibiting, with the concurrence of the Bureau of Insurance, new enrollments into a an MCHIP;
5. Revoking or not renewing a certificate of quality assurance and certifying to the

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Bureau of Insurance that a an MCHIP licensee or its managed care health insurance plan is unable to fulfill its obligations to furnish quality health care services; or

6. Other remedies as provided by state or federal law.

C. The MCHIP licensee shall receive a written notice describing the reasons for the imposition of sanctions and a report specifying the findings of noncompliance. Upon receipt of the notice to impose a sanction, the MCHIP licensee shall have the right and the opportunity to appeal the sanction according to § 32.1-137.5 of the Code of Virginia. A copy of the department's notice shall be provided to the Bureau of Insurance.

12 VAC 5-408-150. Surrender of certificate.

A. Upon revocation or suspension of a certificate or loss of license, the MCHIP licensee must surrender its certificate to a representative of the center.

B. In the event an MCHIP licensee voluntarily ceases operation, it shall provide at least 90 business days advance written notice to all covered persons, employers, providers, the department, and the Bureau of Insurance. The notice shall identify the storage location of business and medical records, where applicable, and procedures for obtaining copies of such records.

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PART II.
Administrative Services.

- 12 VAC 5-408-160. Management and administration.**
- 12 VAC 5-408-170. Provider credentialing and recredentialing.**
- 12 VAC 5-408-180. Complaint system.**
- 12 VAC 5-408-190. Covered person education and communication.**
- 12 VAC 50408-200. Data management.**
- 12 VAC 5-408-210. Medical records.**

12 VAC 5-408-160. Management and administration.

A. No person shall establish or operate a managed care health insurance plan in Virginia without first obtaining a license from the Bureau of Insurance and a certificate of quality assurance from the department.

B. The MCHIP licensee must comply with:

- 1. This chapter;
- 2. Other applicable federal, state or local laws and regulations; and
- 3. The MCHIP licensee's own policies and procedures.

C. The MCHIP licensee shall submit or make available reports and information as described in § 32.1-137.4 of the Code of Virginia necessary to establish compliance with these standards and applicable laws.

D. The MCHIP licensee shall permit representatives from the center to conduct examinations or reviews to:

- 1. Verify application information;
- 2. Determine compliance with these standards;
- 3. Review necessary records, including contracts for delegated services and capitated rate information; and
- 4. Investigate complaints and review appeals procedures.

E. The licensee shall notify the center and providers in writing within 30 days of implementing any material changes affecting the MCHIP licensee, including:

- 1. Mailing address;
- 2. Ownership;

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3. Health care services provided, including any delegated services;
4. Medical director;
5. MCHIP or licensee name;
6. Significant provider network changes; and
7. Any material changes in the quality assurance program, complaint process, or utilization review process.

If more advanced notice of a specific change is required by law for notices to providers or covered persons, notice given to the department under this section shall be no less than notice given to covered persons under the law.

- F. All applications, including those for renewal, shall require:
1. A description of the geographic area to be served with a map clearly delineating the boundaries of the service area or areas;
 2. A description of the complaint system required under § 32.1-137.6 of the Code of Virginia and 12 VAC 5-408-130;
 3. A description of the procedures and programs established by the licensee to assure both availability and accessibility of adequate personnel;
 4. A list of the MCHIP licensee's managed care health insurance plans; and
 5. A description of the MCHIP's quality assurance program.
- G. In addition, applications shall include the following:
1. A detailed description of the MCHIP's prescription drug benefit program, if one is offered;
 2. If the MCHIP requires or performs utilization management, the utilization review plan including a description of the criteria, clinical and therapeutic guidelines, and their derivation or source;
 3. A description of the MCHIP licensee's credentialing process;
 4. The current provider directory so that the department can determine whether it complies with subsection G of § 38.2-3407.10 of the Code of Virginia;
 5. A copy of the MCHIP's evidence of coverage or insurance plan coverage limitations and exclusions and other information provided to covered persons;
 6. A description of all types of payment arrangements that the MCHIP licensee uses to compensate providers for health care services rendered to covered persons, including, but not limited to, withholds, bonus payments, capitation, processing fees, and fee-for-service discounts; and
 7. For those MCHIP licensees that conduct clinical studies, a list of clinical studies with abstracts of study design, objectives and, if available, results as applicable to the type of MCHIP licensee.

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H. A list demonstrating the health care services, as required by law, that the licensee provides, arranges, pays for, or reimburses shall be appropriately integrated throughout the MCHIP's service area. Services shall be based upon prevailing nationally recognized standards of medical practice.

I. The licensee shall have a written policy stating the MCHIP licensee treats covered persons in a manner that respects their rights as well as its expectations of provider and covered person responsibilities. The services shall be accessible to all covered persons, including those with diverse cultural and ethnic backgrounds, and those with physical and mental disabilities.

12 VAC 5-408-170. Provider credentialing and recredentialing.

A. The MCHIP licensee shall establish and maintain a comprehensive credentialing verification program to ensure its providers meet the minimum standards of professional licensure or certification. Written supporting documentation for providers who have completed their residency or fellowship requirements for their specialty area more than 12 months prior to the credentialing decision shall include:

1. Current valid license and history of licensure or certification;
2. Status of hospital privileges, if applicable;
3. Valid DEA certificate, if applicable;
4. Information from the National Practitioner Data Bank, as available;
5. Education and training, including post graduate training, if applicable;
6. Specialty board certification status, if applicable;
7. Practice or work history covering at least the past five years; and
8. Current, adequate malpractice insurance and malpractice history of at least the past five years.

B. The MCHIP licensee may grant provisional credentialing for providers who have completed their residency or fellowship requirements for their specialty area within 12 months prior to the credentialing decision. Written supporting documentation necessary to provisionally credential a practitioner shall include:

1. Primary source verification of a current, valid license to practice prior to granting the provisional status;
2. Written confirmation of the past five years of malpractice claims or settlements, or both, from the malpractice carrier or the results of the National Practitioner Data Bank query prior to granting provisional status; and
3. A completed application and signed attestation.

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- C. Providers provisionally credentialed may remain so for 60 calendar days.
- D. Policies for credentialing and recredentialing shall include:
1. Criteria used to credential and recredential;
 2. Process used to make credentialing and recredentialing decisions;
 3. Type of providers, including network providers, covered under the credentialing and recredentialing policies;
 4. Process for notifying providers of information obtained that varies substantially from the information provided by the provider;
 5. Process for receiving input from participating providers to make recommendations regarding the credentialing and recredentialing process; and
 6. A requirement that the MCHIP licensee notify the applicant within 60 calendar days of receipt of an application if information is missing or if there are other deficiencies in the application. The MCHIP licensee shall complete the credentialing process within 90 calendar days of the receipt of all such information requested by the MCHIP licensee or, if information is not requested from the applicant, within 120 calendar days of receipt of an application. The department may impose administrative sanctions upon an MCHIP licensee for failure to complete the credentialing process as provided herein if it finds that such failure occurs with such frequency as to constitute a general business practice.

The policies shall be made available to participating providers and applicants upon written request.

E. A provider fully credentialed by an MCHIP licensee, who changes his place of employment or his nonMCHIP licensee employer, shall, if within 60 calendar days of such change and if practicing within the same specialty, continue to be credentialed by that MCHIP licensee upon receipt by the MCHIP licensee of the following:

1. The effective date of the change;
2. The new tax ID number and copy of W-9, as applicable;
3. The name of the new practice, contact person, address, telephone and fax numbers; and
4. Other such information as may materially differ from the most recently completed credentialing application submitted by the provider to the MCHIP licensee.

This provision shall not apply if the provider's prior place of employment or employer had been delegated credentialing responsibility by the MCHIP licensee.

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Nothing in this section shall be construed to require an MCHIP licensee to contract or recontract with a provider.

- F. The appropriate credentialing process shall be completed before the provider:
1. Begins seeing covered persons;
 2. Enters into the employment or contractual relationship with the MCHIP licensee; and
 3. Is included in the listing of health care providers as a participating provider in any marketing and covered person materials.

G. The providers shall be recredentialed at least every three years. Recredentialing documentation shall include:

1. Current valid license or certification;
2. Status of hospital privileges, if applicable;
3. Current valid DEA registration, if applicable;
4. Specialty board eligibility or certification status, if applicable;
5. Data from covered person complaints and the results of quality reviews, utilization management reviews and covered persons satisfaction surveys, as applicable; and
6. Current, adequate malpractice insurance and history of malpractice claims and professional liability claims resulting in settlements or judgments.

H. All information obtained in the credentialing process shall be subject to review and correction of any erroneous information by the health care provider whose credentials are being reviewed. Nothing in the previous sentence shall require an MCHIP or MCHIP licensee to disclose to a provider, or any other person or party, information or documents: (i) that the MCHIP or the MCHIP licensee, itself, develops or causes to be developed as part of the MCHIP's credentialing process or (ii) that are privileged under applicable law. The department may require the MCHIP licensee to provide a copy of its credentialing policies.

I. Providers shall be required by the MCHIP licensee to notify the MCHIP of any changes in the status of any credentialing criteria.

J. The MCHIP licensee shall not refuse to initially credential or refuse to reverify the credentials of a health care provider solely because the provider treats a substantial number of patients who require expensive or uncompensated care.

K. The MCHIP licensee shall have policies and procedures for altering the conditions of the provider's participation with the MCHIP licensee. The policies shall include actions to be

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taken to improve performance prior to termination and an appeals process for instances when the MCHIP licensee chooses to alter the condition of provider participation based on issues of quality of care or service, except in circumstances where an covered person's health has been jeopardized. Providers shall have complete and timely access to all data and information used by the licensee to identify or determine the need for altering the conditions of participation.

L. The MCHIP licensee shall retain the right to approve new providers and sites based on quality issues, and to terminate or suspend individual providers. Termination or suspension of individual providers for quality of care considerations shall be supported by documented records of noncompliance with specific MCHIP expectations and requirements for providers. The provider shall have a prescribed system of appeal of this decision available to them as prescribed in the contract between the MCHIP or its delegated service entity and the provider.

M. Providers shall be informed of the appeals process. Profession specific providers actively participating in the MCHIP plan shall be included in reviewing appeals and making recommendations for action.

N. The MCHIP licensee shall notify appropriate authorities when a provider's application or contract is suspended or terminated because of quality deficiencies by the health care provider whose credentials are being reviewed.

O. There shall be an organized system to manage and protect the confidentiality of personnel files and records. Records and documents relating to a provider's credentialing application shall be retained for at least seven years.

12 VAC 5-408-180. Complaint system.

A. Every MCHIP licensee shall establish and maintain a system for the resolution of complaints brought by covered persons, or by providers acting on behalf of an covered person and with the covered person's consent, including complaints regarding availability, delivery, or quality of health care services, or any other matter pertaining to the covered person's contractual relationship or status as a third party beneficiary with the MCHIP.

The system shall include:

1. Written notification to all covered persons of the procedures, including telephone numbers and addresses, for contacting the MCHIP with a complaint and telephone numbers and addresses of the complaint unit of the center and the Office of the Managed Care Ombudsman to help with complaints or appeals;

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2. A description of the process used to investigate and resolve complaints, including specific time lines for each step in the complaint process; and

3. A description of the process used to document and track the status of all complaints and compile the complaint information required to be reported to the department under § 32.1-137.6 C of the Code of Virginia.

B. Time lines for responding to complaints shall accommodate clinical urgency and shall not exceed 30 days from receipt of the complaint. Resolution of complaints shall not exceed 60 days from date of receipt of the complaint.

C. The MCHIP licensee shall keep records of complaints filed including:

1. Complaint identifier, using a unique identification code assigned consistently to the covered person;

2. Date complaint received;

3. A general description of the reason for the complaint;

4. Date of each review and hearing, if any;

5. The number of days to gather the information necessary to resolve the complaint;

6. Date closed;

7. Resolution of the complaint;

8. Record of internal actions necessary as a result of the complaint resolution, as applicable; and

9. Notification to the covered person of the resolution.

D. No covered person who exercises the right to file a complaint or an appeal shall be subject to disenrollment or otherwise penalized due to the filing of a complaint or appeal.

E. Complaint records shall be maintained from the date of the MCHIP licensee's last examination and for no less than five years.

F. A description of the systems for filing complaints and appeals shall be provided to covered persons at the time of enrollment and upon request thereafter.

12 VAC 5-408-190. Covered person education and communication.

A. The MCHIP licensee shall make available to each covered person at the time of enrollment or at the time the contract or evidence of coverage is issued, as required by law and upon request thereafter, policies and procedures applicable to the covered person including, but not limited to:

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1. A statement of covered person's rights and responsibilities;
2. Procedures for obtaining care including:
 - a. Referral and authorization requirements;
 - b. Primary care services;
 - c. Specialty care and hospital services;
 - d. Behavioral services, when the complexity of the covered person's condition requires the knowledge base and expertise beyond those of the primary care provider;
 - e. Emergency services and after-hours coverage, including access to emergency care, and any requirements for prior authorization and payment for out-of-service areas;
 - f. Care and coverage when out of the service area;
 - g. Out-of-network services; and
 - h. Pharmacy services;
3. Procedures concerning the complaint process and the process for appealing adverse decisions affecting covered person coverage benefits;
4. To the extent there are coverage restrictions for changing primary care providers, procedures for changing primary care and specialty care providers including any restrictions on changing providers;
5. All necessary mailing addresses and telephone numbers for seeking information or authorization;
6. The toll-free number for the complaint unit of the center; and
7. Notice of the right to obtain information on types of provider payment arrangements used to compensate providers for health care services rendered to covered persons, including, but not limited to, withholds, bonus payments, capitation, processing fees, and fee-for-service discounts.

B. Lists of all network providers shall be made available to covered persons as required in subsection G of § 38.2-3407.10 of the Code of Virginia.

C. There shall be a mechanism for providing covered person information in plain language that is clearly understood and in the languages of the major population groups served.

D. Covered persons shall be provided an opportunity for input regarding the service provided by the MCHIP and any mechanism for input shall be disclosed to them.

E. There shall be a mechanism for assisting covered persons affected by changes in the MCHIP licensee's service areas or network providers. Such mechanisms may include access to information through an internet website, a toll-free telephone number, an electronic copy of the MCHIP's current provider directory, newsletters or any combination thereof.

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12 VAC 5-408-200. Data management.

A. The data management system shall be reasonable and adequate to assess, measure and evaluate the functions of the quality assurance program.

B. If the MCHIP licensee has healthcare data and information, the data management system, which includes medical records, shall comply with federal and state law and regulations, including the Virginia Health Records Privacy Act (§ 32.1-127.1:03 of the Code of Virginia).

12 VAC 5-408-210. Medical records.

A. The MCHIP licensee shall require that an organized medical record system be maintained by providers that assures the availability of information required for effective and continuous covered person care and for quality received.

B. Medical records shall be confidential. Only authorized personnel shall have access as specified in § 32.1-127.1:03 of the Code of Virginia. Written procedures shall govern the use and removal of medical records and the conditions for release of information. The covered person's written consent shall be required for release of information as required by law.

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PART III.
Quality Improvement Program.

12 VAC 5-408-220. Purpose.

12 VAC 5-408-230. Program requirements.

12 VAC 5-408-240. Quality assurance plan.

12 VAC 5-408-220. Purpose.

The MCHIP licensee shall have a comprehensive, systematic, and organized quality assurance program for the purpose of:

1. Improving covered person's health outcomes;
2. Assuring the quality of the services provided to covered persons;
3. Increasing covered person satisfaction;
4. Maximizing opportunities for MCHIP improvements and minimizing opportunities for errors;
5. Monitoring, measuring and evaluating quality activities; and
6. Satisfying all federal and state reporting requirements.

12 VAC 5-408-230. Program requirements.

A. The MCHIP licensee shall be structured operationally to administer the quality assurance program. The quality assurance operations shall include, but not be limited to:

1. Establishing performance goals designed to improve the quality of health care services provided by the MCHIP licensee and governed by the certificate;
2. Developing a quality assurance plan to implement the goals;
3. Measuring and assessing the MCHIP licensee's performance in meeting the goals;
4. Implementing activities based upon the assessments to improve and maintain performance;
5. Integrating the quality assurance activities of appropriate organizational units, providers, delegated service providers, and the governing body into the quality assurance program and providing feedback to those entities;
6. Enlisting covered person input through sources such as satisfaction surveys, reviews of complaints, appeals, and requests to change providers;
7. Maintaining and documenting the licensee's compliance with state and federal laws, as well as private accreditation requirements, if applicable, that govern the MCHIP licensee's quality assurance program; and

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8. Ensuring that the MCHIP licensee's quality goals are communicated to all appropriate organizational units of the MCHIP licensee and delegated health service entities and made available to covered persons and providers upon request.

B. The quality assurance program shall be managed by professional personnel qualified by training and experience to implement the MCHIP licensee's program goals. The organizational relationship and responsibilities for quality assurance shall be clearly defined.

C. The quality assurance program shall be structured to include:

1. Operations accountable for the quality assurance program;
2. A quality assurance program advisory committee whose members include covered persons and representatives from the operations responsible for quality assurance, utilization management, provider affairs, credentialing, complaints and appeals, customer service, medical records, and data management; and
3. A designated physician or clinical professional appropriate to the type of the MCHIP licensee.

D. The MCHIP licensee shall designate a board-certified physician or clinical professional appropriate to the type of MCHIP to serve as the designated physician or clinical professional.

E. The designated physician, or clinical professional as appropriate to the type of MCHIP licensee, must have substantial involvement in the quality assurance program. Substantial involvement may be evidenced by:

1. Defining the responsibilities and interrelationships for professional services;
2. Coordinating, supervising and overseeing the functioning of professional services;
3. Providing input into the medical performance of providers;
4. Overseeing the continuing in-service education of the MCHIP's professional staff;
5. Providing clinical direction and leadership to the continuous quality assurance program;
6. Establishing policies and procedures covering all health care services provided to covered persons; and
7. Ensuring review of provider credentials including, but not limited to:
 - a. Delineating qualifications for participating in the MCHIP;
 - b. Establishing a system for verification of providers' credentials, recredentialing, performance reviews; and

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c. Obtaining information about any disciplinary action against a provider.

F. The quality assurance program advisory committee shall:

1. Recommend policies for quality assurance;
2. Review and approve the quality assurance program;
3. Evaluate the results of the quality assurance program;
4. Initiate quality assurance activities; and
5. Ensure implementation of the quality assurance program.

G. All determinations and actions made by the committee shall be recorded in minutes that are dated, approved and current.

H. The quality assurance program operations shall maintain written descriptions of the responsibilities of each of the operational units of the licensee and the governing body in the planning, development, implementation and evaluation of the MCHIP licensee's quality assurance program. The descriptions shall include an organizational chart.

I. A written report shall be issued annually by quality assurance operations to the MCHIP licensee's executive management and to the governing body. The purpose of the report shall be to evaluate the MCHIP licensee's quality assurance program activities including, at a minimum:

1. The MCHIP licensee's achievements in meeting its quality assurance expectations;
2. Those areas where expectations were not met or where improvements are still needed;
3. The impact of the MCHIP licensee's quality assurance program, including specific programmatic initiatives, on the quality of care received by covered persons as assessed using reasonable indicators; and
4. New areas identified through the quality assurance assessment process that will be incorporated in the next annual quality assurance program plan.

J. The quality assurance program is accountable to the governing body. Documentation shall be maintained by the MCHIP licensee that the governing body has reviewed the annual quality assurance program report and has provided direction to the program and, as necessary, other operational units in response to the report.

K. A summary of the program shall be provided to appropriate managers, providers and staff members of the MCHIP licensee, and shall be available to covered persons of the MCHIP upon request.

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L. There shall be a mechanism in place to inform covered persons, providers, and employers of the MCHIP licensee's annual performance results each year, upon request.

12 VAC 5-408-240. Quality assurance plan.

Each MCHIP licensee shall have a written quality assurance plan. The plan shall include:

1. The quality assurance performance expectations for the MCHIP licensee for the year and an explanation as to the rationale for targeting these expectations;
2. Delineation of the expected outcomes for the performance expectations;
3. The performance activities to implement the plan and the specific lines of authority and accountability for implementation;
4. The data collection and analysis methodologies to be used to evaluate the quality of services;
5. For MCHIP licensees that have access to clinical data, clinical studies, applicable to the type of MCHIP, that target clinical diagnosis and treatments with the requirement that those diagnoses focused upon are pertinent to a substantial number of its covered persons, or have been identified as major public health risks. The plan shall also include studies that are pertinent to the covered persons of the product lines that the MCHIP manages or that address major public health risks;
6. Strategies to evaluate provider performance and systems, request corrective action when patterns are identified, and act when corrective action has not been taken;
7. Methods to assess covered person satisfaction so as to identify opportunities for improvement and set improvement goals;
8. For MCHIP licensees that have access to clinical data, evaluations of the actual outcomes of care provided to selected groups of covered persons with an analysis of variations in care;
9. For MCHIP licensees that have access to clinical data, amendment of treatment protocols and clinical practice guidelines, as necessary, to make them current and the development of new protocols and clinical practice guidelines, as necessary, to address clinical conditions;
10. Strategies to evaluate the continuity of care that covered persons receive; and
11. Analysis of the accessibility of covered person services including emergency services and after-hour care within the licensee's geographic service area. Compliance may be demonstrated by evidence of contract language with providers stipulating after-hour care, customer satisfaction surveys, and complaint reviews.

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PART IV.
Coordination and Continuity of Care.

- 12 VAC 5-408-250. Continuity of care.**
- 12 VAC 5-408-260. Network adequacy.**
- 12 VAC 5-408-270. Travel and appointment waiting times.**
- 12 VAC 5-408-280. urgent care and emergency services.**
- 12 VAC 5-408-290. Health promotions.**

12 VAC 5-408-250. Continuity of care.

A. The MCHIP licensee shall provide, arrange, pay for, or reimburse the basic health care services it provides in such a way that:

1. Covered persons' individual needs are assessed on an ongoing basis through their physician or staff and matched with the appropriate level of medical, psychological, or medical social services care. The MCHIP licensee shall monitor the continuity and coordination of care a covered person receives with other facets of care;

2. Covered persons' transition through the system of care are facilitated by the MCHIP licensee and its components;

3. The MCHIP licensee does not impede covered persons' involvement in determining care and treatment;

4. Information necessary to support the provision of care from one plan component to another is provided in a timely manner to covered persons and providers to support the continuity of the covered person's care; and

5. The MCHIP licensee advises its physicians of their responsibility to share specific information with covered persons concerning their illness, condition or treatment, in order for the covered person to follow his plan of care and receive follow-up care when needed.

B. The MCHIP licensee shall assist with denial of care issues by providing adequate information for covered person and provider decisions regarding ongoing care, or if appropriate, discharge.

12 VAC 5-408-260. Network adequacy.

A. The MCHIP licensee shall provide a sufficient number and mix of services, specialists, and practice sites to meet covered persons' health care needs, including providers serving high risk populations or those specializing in the treatment of costly conditions, and its contractual obligations with reasonable promptness.

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B. The MCHIP licensee shall ensure covered persons telephone access 24 hours a day, 7 days a week, to responsible and knowledgeable health care practitioners capable of assessing the covered persons' conditions and, as necessary, providing for appropriate services.

C. The MCHIP licensee shall incorporate strategies into its access procedures to facilitate utilization of the licensee's health care services by covered persons with physical, mental, language or cultural barriers.

D. If the MCHIP licensee does not have a health care provider within its network capable of providing care to covered persons, the licensee shall cover such care out of network. The covered person shall not be responsible for any additional costs incurred by the MCHIP as a result of this referral, consistent with the evidence of coverage, other than any applicable copayment, coinsurance or deductible.

E. The MCHIP licensee shall make provisions for affected covered persons to be notified about the termination of a provider as soon as it becomes aware of the termination. The MCHIP shall inform the affected covered persons of other participating providers available to assume their care and facilitate the covered persons' transition from a terminating provider to another provider so that the covered person's continuity of care is not interrupted. Covered persons undergoing an active course of treatment shall have continued access to care during the transition period.

12 VAC 5-408-270. Travel and appointment waiting times.

A. An MCHIP shall set reasonable and adequate standards for the number and geographic distribution of primary care, specialty care, and institutional service sites. Such standards shall address acceptable average travel times or distances to the nearest primary care delivery site, nearest specialty care site, or nearest institutional service site for covered persons in the service area. The standards must be realistic for the community served, the delivery system utilized by the MCHIP, and clinical safety.

Institutional service sites include acute care hospitals, surgical facilities including tertiary care or other specialty hospitals, licensed acute care hospitals and outpatient surgical hospitals, psychiatric inpatient facilities and other sites as determined appropriate by the department.

B. An MCHIP licensee must set reasonable and adequate standards for access to medical care, including quantifiable and measurable standards for preventive care appointments, routine primary care appointments, urgent care, emergency care, and after-hours care. The standards must be realistic for the community served, the delivery system utilized by the MCHIP, and clinical safety.

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C. An MCHIP shall, at least annually, collect and analyze data to measure its performance against the standards developed under subsections A and B of this section. The analysis shall be used by the MCHIP to identify opportunities for improvement and undertake interventions to improve performance. An MCHIP shall subsequently measure the effectiveness of such interventions in improving performance against standards.

D. Routine appointments for nonemergency or nonurgent care shall be available within two weeks of the covered person's request. The department may waive this requirement if the MCHIP licensee can successfully demonstrate that the two-week availability requirement is not feasible.

E. Preventive care appointments, including routine physical examinations, shall be available within 60 days of the covered person's request. The department may waive this requirement if the MCHIP licensee can successfully demonstrate that the 60-day availability requirement is not feasible.

F. Consultations for specialty services shall be at least as required in § 38.2-3407.11:1 of the Code of Virginia.

12 VAC 5-408-280. Urgent care and emergency services.

A. The MCHIP licensee shall require that participating providers allow its covered persons, on a 24-hour basis, (i) access to medical care or (ii) access by telephone to a physician or licensed health care professional with appropriate medical training who can refer or direct a covered person for prompt medical care in cases where there is a need for urgent care or emergency services.

B. The MCHIP licensee shall provide clear and understandable explanation to covered persons and providers of:

1. What constitutes emergency and urgent care;
2. The process for accessing emergency and urgent care;
3. The responsibility of the covered person for payment for nonemergency services rendered in a hospital emergency facility; and
4. Coverage for out-of-network emergency medical care when a covered person cannot reasonably access network services.

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C. The MCHIP licensee shall require its providers to clearly notify covered persons of provisions for urgent care or emergency services when the physician is not available after hours.

D. The MCHIP licensee shall recognize primary care practitioners' authority to facilitate and authorize emergency services for covered persons.

E. Coverage of costs for emergency services shall be consistent with the evidence of coverage and shall not interfere with covered person access to care.

F. Covered persons shall be allowed immediate access to emergency services and access within no more than 24 hours for urgent care. Urgent care access may be provided sooner with appropriate authorization.

G. The MCHIP licensee shall monitor usage of urgent care and emergency service to determine if the services are understood and appropriately used by covered persons and providers.

12 VAC 5-408-290. Health promotion.

A. Annually, the MCHIP licensee shall develop and implement at least one health guideline for the prevention and early detection of illness and disease. Each written guideline shall:

1. Be available to covered persons upon request;
2. Describe the prevention or early detection intervention and the recommended frequency and condition under which the intervention is required; and
3. Document the scientific basis or authority upon which the guideline is based.

Guidelines may be specific to a defined population segment.

B. The MCHIP licensee shall distribute any preventive health guideline it develops and any updates to its providers as soon as practicable after development of the guideline.

C. The MCHIP shall regularly communicate with its covered persons to encourage the use of preventive health services.

D. At least annually, the MCHIP licensee shall measure covered person and provider compliance with the current preventive care guidelines. The MCHIP licensee may measure compliance by population segment if the guideline is specific to a population segment.

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E. Providers who have appropriate knowledge shall be consulted in the adoption of the preventive health guidelines.

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PART V.
Clinical Performance Evaluation.

12 VAC 5-408-300. Clinical performance evaluation systems.

12 VAC 5-408-310. Data collection and submission.

12 VAC 5-408-300. Clinical performance evaluation systems.

A. The MCHIP licensee shall have a system for the evaluation of the outcomes and processes of clinical care services delivered to the MCHIP's covered persons.

B. The MCHIP licensee shall adopt a nationally recognized clinical performance evaluation system, such as the Health Plan Employer Data and Information Set (HEDIS), that analyzes data based upon selected performance factors or shall establish a clinical performance evaluation system that uses data collection, quantitative measures, and analysis to monitor quality improvement activities.

C. The MCHIP licensee shall notify the department regarding its adoption of a nationally recognized clinical performance evaluation system, such as HEDIS, or that it has chosen to establish its own performance measurement system.

MCHIP licensees that choose not to adopt a nationally recognized system shall provide justification to the department of their choice of performance measurement selections for the department's approval.

D. The MCHIP licensee shall annually evaluate its performance in at least three of the areas of clinical care shown below:

1. Primary care services;
2. High volume specialty services;
3. Behavioral health services; and
4. Institutional health services including inpatient hospital care, home health services, skilled nursing facility services and ambulatory surgery.

If HEDIS measures are used to assess clinical performance, the MCHIP licensee shall substitute the HEDIS "Effectiveness of Care" measures for those areas listed in subdivisions 1 through 4 of this subsection.

E. The performance measurement indicators chosen by the MCHIP licensee shall:

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1. Be objective and quantifiable;
2. Be based upon current and reliable scientific information;
3. Have an established goal or benchmark;
4. Effectively measure performance indicators; and
5. Have priority areas for measuring outcomes of clinical care and be reflective of industry-wide performance measurement goals.

F. The MCHIP licensee shall implement ways to improve its performance based on an analysis of its clinical performance measurements.

12 VAC 5-408-310. Data collection and submission.

A. Data collected and analyzed for clinical service evaluation shall be:

1. From the covered person population areas appropriate for the MCHIP to assess including: (i) high risk and high volume areas, (ii) areas where clinical problems are expected or have occurred in the past, (iii) areas that have the potential for adverse health outcomes, and (iv) areas where preventive health measures may have an impact;
2. Collected using processes that are methodologically sound;
3. Valid, reliable, complete and timely;
4. Analyzed quantitatively by personnel qualified to evaluate the data for clinical quality improvement; and
5. Protected for confidentiality, easily retrievable, and transmitted for appropriate release to external parties.

B. The MCHIP licensee may permit appropriate organizations with which it contracts to collect and analyze relevant performance evaluation data and to release that data to the department or to its designee.

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PART VI.
Delegated Services.

- 12 VAC 5-408-320. Delegated services.**
- 12 VAC 5-408-330. Written agreement.**
- 12 VAC 5-408-340. Exchange of information.**
- 12 VAC 5-408-350. Quality assurance program.**

12 VAC 5-408-320. Delegated services.

A. If the MCHIP licensee contracts for any of the following services, it shall retain accountability for the oversight of those services:

1. Quality assurance activities;
2. Credentialing and recredentialing;
3. Covered person education, communication and satisfaction;
4. Utilization management;
5. Health promotion;
6. Records management;
7. Data management;
8. Providers and provider networks;
9. Claims administration; or
10. Pharmacy benefits.

B. The MCHIP licensee shall establish and implement written procedures to evaluate the effectiveness of any delegated service.

C. The MCHIP licensee shall require the delegated service entity to maintain documentation of its compliance with this chapter, its agreement with the MCHIP licensee to provide services, and any applicable state and federal laws.

D. Data and information exchanged between the delegated service entity and the plan shall be accomplished in a manner that is timely, efficient, and effective.

E. The MCHIP licensee shall require the delegated service entity to provide for timely and efficient access by state examiners to data, records, and personnel necessary to determine compliance with this chapter.

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12 VAC 5-408-330. Written agreement.

A. There shall be a written agreement signed by the MCHIP licensee and the delegated service entity that describes the:

1. Delegated service or services;
2. Responsibilities of the MCHIP and the delegated service entity and the remedies available to the MCHIP if the delegated service entity does not fulfill its obligations; and
3. Frequency of reporting to the MCHIP licensee and the process by which the MCHIP will evaluate the delegated service entity's performance.

B. The MCHIP licensee shall ensure that the covered persons' continuity of care is not disrupted because of changes made in the written agreement between the MCHIP licensee and the delegated service entity or because the relationship, as provided for in the agreement, is terminated.

12 VAC 5-408-340. Exchange of information.

A. If the delegated services are health care services, then the delegated services entity or the MCHIP licensee shall make the following information available if requested by the MCHIP's covered persons:

1. The procedures for filing complaints and appeals;
2. The utilization management decision process;
3. The process for appealing claims denials;
4. How to access emergency and urgent care;
5. How to obtain services not covered in the delegated health services' benefit package;
6. The process for changing from one practitioner to another;
7. Orientation process for new covered persons;
8. Covered person participation opportunities; and
9. Participating practitioners and providers.

B. If the delegated services are health care services, then the delegated service entity or the MCHIP licensee shall also inform the MCHIP's providers of at least the following:

1. Opportunities for provider involvement;
2. MCHIP licensee expectations of providers in achieving quality assurance program goals;

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3. Provider credentialing process;
4. Procedures for complaints and appeals;
5. Process for utilization management decisions; and
6. Procedures to approve covered person access to emergency and urgent care.

12 VAC 5-408-350. Quality assurance program.

A. As it pertains to the covered persons, the MCHIP licensee shall integrate monitoring of the delegated service entity with respect to the following activities within its quality assurance program:

1. Quality assurance program activities;
2. Quality assurance plan measures; and
3. Complaint and appeals processes.

B. When the MCHIP's licensee's expectations have not been met, the MCHIP licensee shall require the delegated service entity to provide:

1. A corrective action plan that addresses areas where performance expectations have not been met; and
2. Evidence that corrective action was taken in keeping with corrective action plans.

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PART VII.
Utilization Review and Management.

12 VAC 5-408-360. Utilization review and management.

12 VAC 5-408-360. Utilization review and management.

A. The MCHIP licensee shall have a utilization review and management process that complies with the requirements of §§ 32.1-137.7 through 32.1-137.16 of the Code of Virginia and this chapter. The process shall be managed by a licensed physician.

B. In developing its utilization review program, the MCHIP licensee shall utilize the applicable utilization review and management standards of the American Accreditation HealthCare Commission/URAC or the National Committee for Quality Assurance or other nationally recognized accrediting body acceptable to the department, as the criteria for determining compliance with the utilization management and review requirements of this section except in those instances in which state requirements in law or regulation are more stringent. Applicable utilization review and management standards are those included in an accreditation or certification program for a specific type of MCHIP, such as health maintenance organizations or preferred provider organizations, or for utilization review entities such as private review agents licensed in Virginia, to which MCHIPs may delegate utilization review and management services.

C. The MCHIP licensee, or its contracted private review agent or other delegated service entity for utilization review and management services, may demonstrate compliance with the utilization management and review requirements of this section by attaining accreditation or certification with the American Accreditation HealthCare Commission/URAC, the National Committee for Quality Assurance, or other nationally recognized accrediting body with comparable standards for utilization review accepted by the department. The department may require the MCHIP to demonstrate compliance with particular requirements of §§ 32.1-137.7 through 32.1-137.16 of the Code of Virginia, as well as any other pertinent sections, and this chapter that are more stringent than the applicable accreditation requirements. The department may provide a checklist or other standardized method by which MCHIP licensees may demonstrate compliance with the more stringent requirements.

D. An MCHIP licensee that is not accredited by a nationally recognized accrediting body and accepted by the department shall be subject to the triennial comprehensive onsite examination requirements of 12 VAC 5-408-90 for purposes of demonstrating compliance with the utilization review and management requirements of this section.

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E. The purpose of the utilization review process shall be to monitor access to and utilization of health care services with the process ensuring that the conduct of utilization review is:

1. Impartial, timely, consistent and based upon supportive medical evidence;
2. Performed by appropriately qualified health personnel;
3. Comprehensive in assuring that good faith efforts to obtain all information necessary to make utilization review decisions are made;
4. Evaluated routinely so that program changes that determine the necessity, appropriateness, efficiency and efficacy of health care services provided by the MCHIP licensee can be made as a result of the evaluation; and
5. Reported annually to the MCHIP licensee's governing body.

F. In addition, the utilization review process shall:

1. Allow for flexibility, taking into account individual cases when appropriate;
2. Provide avenues for provider input into the establishment of clinical guidelines and protocols;
3. Afford opportunity for reconsideration and appeal of adverse determinations in a manner that is easily understood and accessed by covered persons and providers; and
4. Be coordinated with other components of the MCHIP that use or could benefit from utilization review data.

G. The utilization review process shall be based upon a written plan that is reviewed annually and that shall contain, at a minimum:

1. A description of the scope of the utilization review process, both internal and external;
2. A description of the organizational responsibilities for utilization review including the qualifications of utilization review personnel;
3. The clinical review guidelines, standards, and protocols which are applied in utilization review determinations;
4. Mechanisms to evaluate uniform application of guidelines and to determine the necessity for case-by-case decision making;
5. Procedures for soliciting and implementing provider input in the development of guidelines as well as evaluating provider usage of the guidelines;
6. A description of the process for monitoring over utilization and under utilization;
7. Provisions for notice to covered persons and providers regarding any need for

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precertification, concurrent certification, or retrospective review as a prerequisite for approval of payment or access to service;

8. Procedures for reconsideration of adverse decisions and appeals including expedited appeals;

9. Guidelines for the delegation of utilization review to external entities and the expectations for that delegation;

10. Guidelines for the notification in clear and understandable terms of the reasons for denial of services or payments to providers and subscribers;

11. Mechanisms for review and implementation of experimental treatments and new technology;

12. Mechanisms for soliciting and evaluating provider and covered person satisfaction with utilization review determinations and the MCHIP licensee's appeal process and implementing mechanisms to address areas of dissatisfaction; and

13. Procedures for the maintenance of records required under § 32.1-137.16 of the Code of Virginia.